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OIG's Expansion of Anti-Kickback Safe Harbors Reflects a Limited Acceptance of Changes in Provider Organization and Delivery of Care

William A. Sarraille, JD*, and Robert Wanerman, JD#

On November 19, 1999, the Health and Human Services (HHS) Office of Inspector General (OIG) published a final rule, adding eight new anti-kickback safe harbors and clarifying six of the existing safe harbors (1). The new and revised safe harbors are the first major revisions to the regulations since they were first published in 1991 and have been under consideration by the OIG for over five years. Among the changes are several provisions that may affect pain management practices in a variety of clinical settings. This article will focus on the impact of those changes, and whether practices need to review their existing agreements for compliance purposes.

A. Introduction to the Federal Anti-Kickback Law and Related Laws

Under the federal health care anti-kickback law, which was first enacted in 1972, it is a felony to knowingly and willfully offer, solicit, pay or receive anything of value, whether directly or indirectly, in exchange for or to induce the referral of items or services for which a federal health care program may make payment (2). Violations of the law are punishable by criminal fines of up to $25,000 per offense, incarceration for up to five years, or both. In addition, a violation of the anti-kickback law may trigger two civil sanctions: first, the OIG may exclude the offending individual or entity from participation in the Medicare and Medicaid programs; second, the OIG can impose a civil monetary penalty of $50,000 per violation, plus up to three times the amount of the underlying remuneration (3).

In 1987 Congress recognized the extraordinary breadth of the anti-kickback law and amended it to require the Secretary of HHS to publish regulations that specify those payment practices that will not be exempted from the reach of the law. Any transaction that fits squarely within the published "safe harbors" is not subject to prosecution or sanction; all others will be evaluated on a case-by-case basis to determine if a violation has occurred and if enforcement is warranted.

The first group of safe harbors published in 1991, covered ten areas, including investment interests, rentals of space and equipment, personal service and management agreements, sales of practices, payments to employees, discounts, and referral services. The next year, safe harbors covering managed care arrangements were published. By 1996, the numerous changes in health care delivery led Congress to mandate that the OIG publish annual solicitations for both modifications to existing safe harbors and for new safe harbors.

The conduct targeted in the anti-kickback law and the exceptions overlap with the Stark anti-referral law, named for its primary sponsor in Congress (4). However, the two are distinct and should not be confused. Under Stark, a physician is prohibited from referring a patient to an entity in which he or she (or a member of the physician's immediate family) has either an ownership interest or compensation arrangement for one of a list of "designated health services" that may be covered under Medicare unless a specific exception in the law applies to the circumstances (5).

If a referral is made by a physician for a designated health service and that physician (or an immediate family member) has an ownership interest or compensation arrangement in the entity receiving the referral that is not permit-

From Arent Fox Kintner Plotkin & Kahn, PLLC, Washington, DC. *Mr. Sarraille is a partner in the Washington, DC and New York, NY law firm of Arent Fox. He serves as AOPMA's General Counsel. #Mr. Wanerman is a senior associate with Arent Fox. Address correspondence: William A. Sarraille, Esq., Arent Fox, 1050 Connecticut Avenue, Washington, DC 20036

ted under the statute, then the physician is exposed to a range of sanctions. Payment for the services rendered must be denied, and the physician may be subject to civil monetary penalties and to exclusion from participation in the Medicare and state health care programs (6).

Many of the Stark exceptions cover the same ground as the anti-kickback safe harbors, such as investment interests, rental of space and equipment, personal service agreements and payments to employees. However, the scope of the exceptions are not always identical. For this reason, several commentators suggested that the OIG amend the existing safe harbors to conform to the Stark exceptions. The OIG did not make these changes, citing the differences in the scope and structure of the two laws. The anti-kickback law gives offenders a criminal statute, and the intent of the parties is a key element of any violation; consequently, the Stark law is a civil statute, and the intent of the parties is irrelevant. Similarly, if a transaction does not fit within an anti-kickback safe harbor, it is not necessarily illegal; however, the failure to fit within a Stark exception is a violation of that law. The OIG further noted that it is possible for a transaction to violate the anti-kickback law even if the agreement satisfies a Stark exception.

In addition to the federal laws, many states have enacted counterparts to the anti-kickback and anti-referral laws. These laws should also be consulted to fully assess whether or not a particular transaction poses a financial risk to the practice.

B. The New and Revised Safe Harbors

As discussed above, a comprehensive treatment of each of the new and revised safe harbors is beyond the scope of this article. In addition to the specific revisions discussed below, the OIG crafted a set of safe harbors designed to provide incentives, including investments in practices located in medically-underserved areas and for recruiting practitioners to provide services in those areas. In addition, the OIG also approved certain payments made between hospitals and cooperative hospital service organizations.

Due to the changes made in the scope of regulatory protection, the OIG also considered comments that sought to establish a "grace period" for practitioners to revise existing agreements so that they conform to the revised safe harbors. Although the OIG did not include an express "grace period " based on its belief that the reasonable time period will vary based on the nature and complexity of the agreement involved, it did state that if the parties reasonably believed that an existing agreement met one of the old safe harbors and acted promptly to revise the agreement to conform to a new or revised safe harbor, then the OIG will attempt to be fair to the parties.

1. Ambulatory Surgical Centers

The new regulations establish a safe harbor for investments in ambulatory surgical centers (ASCs). Given the variety of ASCs, the OIG has identified four distinct entities that qualify for safe harbor protection: surgeon-owned ASCs, at which all physician-investors are either general surgeons or group practices composed of surgeons engaged in the same specialty with the ability to refer patients; single-specialty ASCs, where all physician-investors are engaged in the same specialty or subspecialty, such as pain management anesthesiology; multi-specialty ASCs, where the physician-investors can be a mix of specialties, including many mixed group practices; and hospital-physician ASCs, where the investors consist of at least one hospital and physicians, group practices or non-referral sources.

In each category, safe harbor protection for an ASC is available if the investors also include individuals or entities without any ability to refer patients to the ASC or to generate business either for the ASC or any of its investors. In the OIG's view, the key to ASC safe harbor is to protect those investments that represent a legitimate extension of the physician's or group's office practice.

In order to qualify for safe harbor protection, the minimum criteria that an ASC must meet include:

- certification under the Medicare program (including a requirement that the operating and recovery space in the facility be dedicated exclusively to the ASC)
- full disclosure of any physician investment interest to a program beneficiary who may be referred to the ASC
- no investment in the ASC can be made with funds loaned from the ASC or from other investors
- investment interests in the ASC cannot be offered on terms linked to the value or volume of referrals to the ASC
- all payments to investors must be directly proportional to the individual's or

entity's capital investment in the ASC (including the fair market value of any pre-operative services rendered)
- all ancillary services must be a integral part of the primary procedure performed at the ASC, and cannot be billed separately to Medicare or to any federal health care program
- neither the ASC nor physicians practicing at the ASC may discriminate against federal health program beneficiaries

In addition, for the surgeon-owned, single-specialty, and multi-specialty ASCs, the OIG requires that each of the physician-investors derive at least one-third of their aggregate medical practice income from all sources during the preceding fiscal year or 12-month period from performing procedures covered by Medicare that require an ASC setting. Under the OIG's view, if an ASC represents an extension of a traditional office practice, then there is a minimal risk that the referring physician will refer patients to other investors. However, the rule does **not** mandate that the physician-investor derive at least one-third of his or her income from procedures performed at the ASC in which he or she has an investment interest. While this may appear to contradict the concept of an ASC as an extension of the office practice, it makes it easier to satisfy this requirement and allows for variations in such factors as quality, scope of specialty and convenience for the patient.

In addition to the "one-third income" test for ASCs, the OIG added an additional burden for multi-specialty ASCs. In order to minimize the potential for abusive cross-referrals within multi-specialty groups, each member of this category of physician-investors must also meet the requirement that at least one-third of his or her procedures that require an ASC or hospital surgical setting be performed at the ASC in which each group member is investing. Thus, in order to comply with the "one-third-income" and "one-third procedures" tests in this safe harbor, some multi-specialty group practices may actually be forced to "lock in" a referral mechanism.

This restriction may be particularly frustrating, since the safe harbor will not protect an ASC owned by a specialty group practice if any member of the group does not derive at least one-third of his or her medical practice income from surgical or other procedures performed in the ASC. As a result, if a practice consisting of three anesthesiologists owns and operates an ASC and if one of these anesthesiologists concentrates in surgical anesthesiology and rarely performs pain management procedures at the ASC, that ASC may not qualify for safe harbor protection, unless this anesthesiologist is considered not to be in a position to refer, a point not addressed in the final rule. In addition, the literal language of these safe harbors does not include practices owned by physicians and mid-level practitioners, such as CRNAs.

The new regulations take a more skeptical view of ASCs that are joint ventures between hospitals and physicians or physician groups. In the preamble to the regulations, the OIG stated its belief that such joint ventures are often susceptible to fraud and abuse. Nevertheless, in order to avoid placing hospitals at a competitive disadvantage, it will extend safe harbor protection to hospital/physician ASCs under limited circumstances. In addition to the limits discussed above governing the terms of the investment and the payments to investors, safe harbor protection is available for hospital/physician ASCs only if the hospital cannot be in a position to make or influence referrals to the ASC or to any of the investors in the ASC.

However, this requirement may effectively render the safe harbor meaningless, as OIG takes the position that hospitals can and do exercise referrals to ASCs. This problem may be avoided if the hospital expressly states in its by-laws or in any joint venture agreement that it will not interfere in any way with the exercise of a physician's judgment involving referrals and will not take any action to advertise or otherwise market the ASC. The safe harbor rule does not state whether even these precautions would be sufficient.

Under the hospital/physician ASC safe harbor, the physical space for the ASC must be dedicated space and cannot be used to treat the hospital's outpatients. If the space for the ASC or the equipment used in the ASC is leased from the hospital, or if the hospital provides services to the ASC, then these agreements must also satisfy the existing safe harbors for space rental, equipment rental, or personal services and management contracts as set out in other safe harbors (7). Finally, the hospital cannot include the costs associated with the ASC on its cost report unless expressly authorized by HCFA.

As discussed above, the OIG's rationale for extending safe harbor protection to ASCs is that they represent a legitimate extension of a physician's or group's office practice. Yet, the OIG's application of this reasoning appears to be inconsistent and artificially restrictive. While the OIG

received comments urging it to include other entities within the scope of this safe harbor based on the "extension of practice" concept, it declined to do so. The OIG's reasoning was that these entities, including physical therapy centers and diagnostic imaging centers, do not provide a cost savings to the programs when compared with hospital inpatient and outpatient surgery departments. By doing so, the OIG refused to recognize that many of these other entities are genuine extensions of specialty practices and, when operated as free-standing entities, may deliver these services more efficiently and economically than their hospital-based counterparts.

Another anomaly in the revised safe harbors is the imposition of a requirement that physician-owned ASCs must disclose their ownership interests, while other physician-owned entities that qualify for protection under the small entity safe harbor need not make the same type of disclosure (8). Moreover, the safe harbors take inconsistent positions when it comes to separately billable ancillary services. While these services are not separately billable under the ASC safe harbor, they are protected under another safe harbor. These inconsistencies may produce the unintended result that ASCs may be unwilling or unable to compete effectively with hospitals over a broader range of services than just surgical and other procedures.

2. Investment Interests in Group Practices

In most group practices, the total income of the group is shared among its members or shareholders. Part of that pooled income often includes income generated as the result of a referral from one group member to another. It was unclear before the final rule was issued if that fact had any potential anti-kickback law implications. Although some have welcomed the group-practice safe harbor, others question why it was developed and have expressed concern that the existence of such a safe harbor implies that even internal group practice arrangements are not free from scrutiny under the anti-kickback statute.

A new safe harbor expressly protects investments by individual physicians in group practices provided that the practice meets the definition of a group practice in the Stark law, with some modification. Under that law, a physician who has an ownership interest in or a compensation arrangement with a group practice will not violate that law if he or she makes a referral to that group for a designated health service payable under Medicare or a state health care program, where certain conditions are met (9). Under the safe harbor, a qualifying group may consist of individual licensed professionals who practice in a group or of a solo practice in which the solo practitioner's professional corporation provides the services.

One notable omission from the scope of this safe harbor is the inclusion of mid-level practitioners, such as CRNAs, nurse practitioners and clinical nurse specialists, as potential investors when permitted by state law. The OIG's reasoning was that because it was incorporating the Stark law exception, which only addresses financial interests of physicians, it was not prepared to go beyond the scope of that law. Nevertheless, the OIG did not foreclose a possible broadening of this safe harbor in its future rulemaking.

In order to qualify for this safe harbor, the equity interests in the group must be held by licensed professionals (or an individual professional corporation in the case of a solo practice) who practice in the group. Investment interests that take the form of bonds, notes or other debt instruments are not considered in determining whether or not safe harbor protection is available; as a result, an equity interest in a group practice could be acquired with a loan from the group without jeopardizing the safe harbor protection. The equity interests must be in the group itself and not in a subdivision of the group.

Finally, any distribution of profits derived from in-office ancillary services will be protected only if those services meet the Stark law's definition of in-office ancillary services (10). The OIG was particularly concerned that investments by members of a group practice in entities that provide ancillary services created the potential for overutilization and abuse of those services. As a result, an investment by a pain management practice in a physical therapy company will not qualify for safe harbor protection. Nevertheless, the OIG did acknowledge that while this safe harbor might not be available for ancillary service providers, the investment interest might still qualify for the small entity safe harbor, which was amended in the same rulemaking package.

3. Referral Agreements for Specialty Services

Physicians may refer patients to a specialist or subspecialist with the expectation that the patient will be referred back when the patient has reached a particular level of recovery. For example, an orthopedist or neurologist may refer a patient for pain management services with the understanding that the patient will be referred back in the future. Surprisingly, the anti-kickback law does not define the term "referral," even though offering or receiving any-

thing of value in exchange for a referral is a crime.

The new safe harbor insulates those agreements in which a practitioner (or specialist) agrees to refer particular patients to a specialist or subspecialist in exchange for referring the **same** patient back at an agreed time or circumstance that is clinically appropriate. The referral must cover a service that is outside the scope of the referring practitioner's expertise but is within the expertise of the practitioner receiving the referral. The only permissible remuneration in this setting is the payments received from patients or third-party payers (including Medicare or Medicaid). Although the proposed rule would have extended the safe harbor protection to referrals between primary care physicians and specialists who split a global fee under a co-management arrangement, the OIG deleted this proposal from the final rule on the belief that the potential for abuse was too great. Accordingly, safe harbor protection is not to be available where the parties bill the Medicare program using the -54 or -55 modifiers to designate a split of a global fee. As the OIG reiterated, such practices are not necessarily illegal. The only inference that can be drawn is that splitting a global fee is not insulated from possible review by the government.

The OIG's concern that there was an unacceptable risk of abuse involving cross-referrals when the payment made is a global fee that may be split among practitioners in accordance with HCFA's reimbursement rules is surprising. By excluding these arrangements from the safe harbor, the OIG has taken inconsistent positions without tangible evidence of any greater risk of fraud or abuse when a global fee is split between two practitioners.

C. Clarifications to Existing Safe Harbors

1. Investment Interests

A safe harbor currently provides protection for investments in large entities traded on a national securities exchange (those with a capitalization of at least $50 million) and small entities that satisfy the "60-40" rules (i.e., no more than 40% of the investment interests may be held by individuals in a position to refer to the entity, and no more than 40% of the gross revenues may be derived from referrals generated by investors) (11).

The clarifications specify that for investments in large entities, the investment interest must be obtained on the same terms as those available to the public through a securities broker. The OIG was particularly concerned that some health care companies had acquired physician practices in exchange for stock or stock options valued at special insider prices. In the OIG's view, the spread between the market price and the insider price could be a vehicle for hiding payments for referrals. Under the final rule, however, stock and stock options may be protected by the safe harbor protection even if they are provided as compensation to physicians when the public could only acquire similar interests through a stock exchange transaction.

For small entities, the OIG amended the rule to prohibit loans made to an investor by individuals or entities acting on behalf of the investment entity. The safe harbor also precludes loan guarantees or collateral assignments on behalf of the health care entity in order to allow an investor to obtain a bank loan for the purpose of acquiring the investment interest in the entity. The preamble expressly includes prohibitions on loans by hospitals, nursing homes or other institutions in this category. The preamble also clarifies that the analysis under the 60-40 revenue test refers to revenue related to the furnishing of health care items or services.

2. Space Rental, Equipment Rental, and Personal Service and Management Contracts

The OIG published two clarifications to the existing safe harbors covering rentals and service contracts (12). First, it substituted the word "term" for "period" when describing the length of any agreement. Second, in the context of the requirement in the safe harbors that the agreement or contract serve a "legitimate business purpose," the OIG substituted the phrase "commercially-reasonable business purpose" when describing the use of the rented space, equipment or services. The OIG explained that it was shifting the test under these safe harbors to examine whether or not the underlying agreement serves a commercially-reasonable business purpose of the lessee or purchaser. This can be viewed as a restriction on the old safe harbor, since a legitimate business purpose need not depend on measurements of the amount of space or equipment needed for the renter's or lessor's business. Therefore, the definition of what is commercially reasonable is not entirely subjective; if the OIG were to see that a portion of the space, equipment or services involved was not reasonably calculated to further the lessee's or purchaser's commercially-reasonable business objectives, it might conclude that safe harbor protection was not warranted. In addition, the preamble expressly excludes cost-or risk-sharing arrangements, joint research programs and data collection

arrangements from the scope of its definition of "commercially-reasonable" business objectives.

In the OIG's discussion of these new rules, it provided some practical guidance covering the ability of an entity to terminate a contract or lease while not violating the provision in these safe harbors that the underlying agreement have a term of at least one year. It stated that a termination "for cause" can still comply with the safe harbor if the agreement defines the conditions that permit a termination "for cause," and also specifies that the terms of the agreement (or any other financial arrangement between the parties) cannot be renegotiated during the term of that agreement. The OIG refused to recognize any set of circumstances under which safe harbor protection would still be available if an agreement were terminated without cause. Notwithstanding the OIG's concern that terminations without cause could camouflage payments under a sham agreement, that ability could provide an incentive for lessors or management companies to impose onerous terms on providers by expanding the scope of "for cause" termination clauses.

3. Discounts

The existing safe harbor for discounts was clarified in two important respects (13). First, the OIG specifically extended safe harbor protection to rebate programs--defined as any discount that is not given at the time of the sale--involving all types of providers. The rebate terms must be disclosed to the buyer at the time of the initial sale or first installment sale. Second, the OIG clarified the obligations that a seller must meet to comply with the safe harbor. If the seller reports the discount to the buyer and provides the buyer with a notice reasonably calculated to inform the buyer of its obligation to inform the federal health care programs of the discount, the seller will be protected notwithstanding any failure by the buyer to perform in accord with the safe harbor.

The OIG provided additional technical amendments to the discount safe harbor that may make it easier to implement and administer. It noted that the obligation of charge-based buyers to disclose the amount of the discount on any claims submitted to federally-funded health care programs was being eliminated. In addition, the OIG acknowledged that there are economic benefits to offering a discount on one good or service in order to provide an incentive to purchase another good or service provided by the same source, where the net value of the goods or services can be reported; in such cases, the buyer may be able to take advantage of lower prices offered as part of a volume discount. Finally, the OIG stated that safe harbor protection is available for coupons and credits but are not available for discounts that are made available to one class of buyer and not made available to the federal health care programs. The latter point is consistent with the OIG's policy that discounts or other inducements offered by clinical laboratories to hospitals for private pay or HMO patients in the hope of capturing their Medicare and Medicaid business is a potential anti-kickback violation.

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The additions and amendments made by the OIG to the anti-kickback safe harbors, to varying degrees, recognize the pace of changes in the structure and organization of health care providers brought about by changes in reimbursement by government and private payers, as well as changes initiated by the expanded enforcement of fraud and abuse laws by the OIG. Although the changes are far from complete, or even fully acknowledge the benefits of many legitimate practices, the new and revised safe harbors are a beginning. At a minimum, practices should carefully evaluate any agreements affected by the changes in the regulations and may wish to revisit proposed transactions to determine if they now qualify for safe harbor protection.

References

1. 64 Federal Register 63,518 (Nov. 19, 1999).
2. 42 U.S.C. § 1320a-7b(b).
3. 42 U.S.C. §§ 1320a-7(b)(7) and 1320a-7a(a) (7).
4. 42 U.S.C. § 1395nn.
5. The Stark "designated health services" include physical therapy services, radiology services, durable medical equipment and supplies, home health services, outpatient prescription drugs, and inpatient and outpatient hospital services.
6. 42 U.S.C. § 1395nn (g).
7. 42 C.F.R. § 1001.952(b) - (d).
8. The small entity safe harbor is codified at 42 C.F.R. § 1001.952(a).
9. 42 U.S.C. § 1395nn(h) (4).
10. 42 U.S.C. § 1395nn(b) (2).
11. 42 C.F.R. § 1001.952(a).
12. 42 C.F.R. §§ 1001.952(b) - (d).
13. 42 C.F.R. § 1001.952(h).